REMARKS

Introductory Comments:

Claims 21-23 and 25-29 were examined in the Office Action under reply and stand variously rejected under 35 U.S.C. § 112, first paragraph (claims 21-23 and 25-29); 35 U.S.C. §102 (claims 22 and 24-29); and 35 U.S.C. §103 (claims 22 and 24-29). Additionally, claims 22 and 24-29 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting. These rejections are respectfully traversed as discussed more fully below.

Applicant notes with appreciation the withdrawal of the previous rejections under 35 U.S.C. §112, second paragraph; as well as the withdrawal of the previous rejection of claims 21-23 and 25-29 under 35 U.S.C. §112, first paragraph.

Overview of the Above Amendments:

The specification has been amended at page 6, to correct obvious typographical errors.

Claim 25 has been cancelled and recitations therefrom incorporated into independent claims 22 and 23. Thus, all claims now recite a fragment of an unglycosylated, transmembrane protein wherein the fragment lacks a functional portion of a transmembrane domain. Additionally, claim 26 has been amended to include the step of "cleaving a functional portion of a transmembrane domain out of the recovered material." Support for the foregoing amendments can be found throughout the previous claims and specification at, e.g., page 3, line 38 through page 4, line 1; and page 6, lines 15-18.

Cancellation of claim 25 and amendment of claims 22, 23 and 26 is made without prejudice, without intent to abandon any originally claimed subject matter, and without intent to acquiesce in any rejection of record. Applicant expressly reserves the right to file one or more continuing applications hereof containing the canceled or unamended claims. Moreover, the foregoing

amendments do not present new issues or require a new search. Thus, entry thereof is respectfully requested.

Rejection under 35 U.S.C. §112, First Paragraph:

The Office rejected claims 21-23 and 25-29 under 35 U.S.C. §112, first paragraph, based on the use of the recitation "a pharmaceutically acceptable carrier." The Office asserts: "For the claims to be enabled, the specification must teach how to use the composition for at least one pharmaceutical use without undue experimentation. The only pharmaceutical use disclosed is as a treatment for a patient infected with HCV." Office Action, page 4. However, applicant believes these claims to be fully enabled for reasons of record.

Claim 21 has been cancelled. With respect to the remaining claims, as previously explained, the specification is clear that there are multiple uses for the proteins and compositions of the invention. For example, page 7, line 19 through page 8, line 21 explains that the proteins are useful in diagnostic assays for HCV infection, e.g., in ELISAs or RIAs and in other competitive assays. In fact, the Office recognizes the term "pharmaceutically acceptable carrier" encompasses various solutions and buffers, such as PBS. See, Office Action, page 6, second full paragraph. Such buffers are traditionally used in diagnostic tests and the like. Thus, compositions including a pharmaceutically acceptable carrier are not only useful in the context of therapy but are indeed intended for other uses, such as in diagnostic assays.

Nevertheless, should the Examiner decide to maintain this rejection, Applicant authorizes removal of the term "pharmaceutically" from the claims by Examiner's amendment.

Accordingly, withdrawal of this basis for rejection is respectfully requested.

Rejections Over the Art:

The Office maintained the rejection of claims 22 and 24-29 under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as unpatentable over Levy et al. (1991) *J. Biol. Chem.* 266:14597-14602 ("Levy"). The Office has clarified that Levy et al. (1998) *Annu. Rev. Immunol.* 16:89-109 and Pileri et al. (1998) *Science* 282:938-941 were not cited against the application but were given "as evidence of the identification of TAPA-1 and CD81 as the same protein and of the inherent properties of TAPA-1." The Examiner argues that TAPA-1 described in Levy is CD81 and that the recitation of a "pharmaceutically acceptable carrier" does not distinguish from Levy's "various solutions and buffers in which TAPA-1 appears (phosphate buffered saline or resuspension buffer, e.g.)" Office Action, page 6. However, applicant submits that Levy fails to either anticipate or render obvious the claimed invention.

The law is clear that in order to anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 USPQ 81, 90 (Fed. Cir. 1986). *Atlas Powder Co. v. E. I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 411 (Fed. Cir. 1984). Moreover, the single source must disclose all of the claimed elements "arranged as in the claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989); *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1548, 220 USPQ 193, 198 (Fed. Cir. 1983). Finally, the law requires identity between the claimed invention and the prior art disclosure. *Kalman v. Kimberly-Clar Corp.* 713 F.2d 760, 771, 218 USPQ 2d 781, 789 (Fed. Cir. 1983, cert. denied, 465 U.S. 1026 (1984)).

Levy does not describe a composition as claimed and therefore cannot anticipate the present claims. In particular, Levy does not teach or suggest obtaining a fragment of CD81 (i.e., a truncated CD81 protein that lacks a functional portion of a transmembrane domain), and combining the fragment with a pharmaceutically acceptable excipient as claimed. Thus, Levy does not anticipate the present claims and the withdrawal of the rejection over 35 U.S.C. §102(b) is respectfully requested.

Neither does Levy render obvious the invention. It is well settled that *prima facie* obviousness can only be established if the following three basic criteria are met: (1) there must be some suggestion or motivation to modify the reference; (2) there must be a reasonable expectation of success (for the modification and/or combination); and (3) the prior art reference(s) must teach or suggest all the claim limitations. MPEP §2143. Further, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. *In re Vaeck,* 20 USPQ2d 1438 (Fed. Cir. 1991). The Office has not satisfied these criteria.

In particular, as explained above, Levy does not teach or suggest the particular CD81 fragment present in the composition, namely, a truncated CD81 fragment that lacks a functional portion of a transmembrane domain. Moreover, as previously explained to the Examiner, Levy did not understand the significance or function of his TAPA-1 protein. The last paragraph of Levy states: "The functions of the TAPA-1 related family of proteins are currently unknown." Thus, Levy fails to provide a motivation to formulate the protein into a composition since the function of the protein is unknown. The fact that Levy's protein may have the "inherent property" of binding HCV E2 is of no import. It is axiomatic that a retrospective view of inherency, such as proposed by the Office, is not a substitute for some teaching or suggestion to arrive at the claimed invention. That which may be inherent is not necessarily known, and obviousness cannot be predicated on the unknown. See, e.g., *In re Newell*, 13 USPQ2d 1248 (Fed. Cir. 1989).

Without a suggestion to modify Levy evident in this reference, the only conclusion supported by the record is that the rejection was made impermissibly using hindsight reconstruction of the invention. As stated by the Court of Appeals for the Federal Circuit, "[i]t is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious." *In re Fritch*, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992). See, also, *In re Fine*, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988): "One cannot use hindsight

reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

Applicant submits, therefore, that the rejection under 35 U.S.C. §103 should also be withdrawn.

The Obviousness-type Double Patenting Rejection:

Claims 22 and 24-29 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 17 of USSN 09/011,910 and claims 7 and 27-31 of copending USSN 09/509,612. Applicant will consider the propriety of filing a Terminal Disclaimer once allowable subject matter is indicated.

CONCLUSION

Applicant respectfully submits that the claims define a patentable invention. Accordingly, a Notice of Allowance is believed in order and is respectfully requested.

Please direct all further written communications in this application to:

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